



IFW

Docket No.: 3691-0133PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Takashi NISHIMURA et al.

Application No.: 10/583,860

Confirmation No.: N/A

Filed: June 21, 2006

Art Unit: Not Yet Assigned

For: PROCESS FOR PRODUCING ENGINEERED  
TARGETED T CELL AND MEDICINE

Examiner: Not Yet Assigned

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

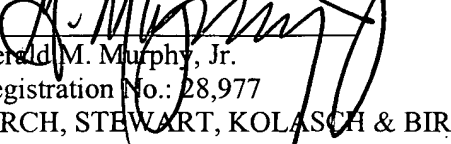
Sir:

Subsequent to the filing of the above-identified application on June 21, 2006, attached hereto is an English Translation of the International Preliminary Report on Patentability issued by the International Bureau on behalf of the International Searching Authority. Please make this document of record for the above-identified application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: September 25, 2006

Respectfully submitted,

By   
Gerald M. Murphy, Jr.  
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Attachment

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

OHNO, Seiji  
OHNO & PARTNERS, Kasumigaseki Building 36E, 2-5,  
Kasumigaseki 3-chome, Chiyoda-ku, Tokyo  
1006036  
JAPON



Date of mailing (day/month/year) 31 August 2006 (31.08.2006)	
Applicant's or agent's file reference PHT-9002WO	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/019714	International filing date (day/month/year) 22 December 2004 (22.12.2004)
Applicant HOKKAIDO TECHNOLOGY LICENSING OFFICE CO., LTD. et al	

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PHT-9002WO	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2004/019714	International filing date ( <i>day/month/year</i> ) 22 December 2004 (22.12.2004)	Priority date ( <i>day/month/year</i> ) 22 December 2003 (22.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant HOKKAIDO TECHNOLOGY LICENSING OFFICE CO., LTD.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 5 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 40%;">Box No. I</td> <td style="width: 50%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. VII	Certain defects in the international application																							
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 22 August 2006 (22.08.2006)
Facsimile No. +41 22 338 82 70	Authorized officer  <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div> e-mail: pt07@wipo.int

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**PHT-9002WO**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/019714**

International filing date (day/month/year)

**22.12.2004**

Priority date (day/month/year)

**22.12.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**HOKKAIDO TECHNOLOGY LICENSING OFFICE CO., LTD.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019714

Box No. I      Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language

\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☒

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed.

☒

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019714

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 20-21

because:

☒ the said international application, or the said claims Nos. 20-21

relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions of Claims 20-21 relate to a method for treatment or diagnosis of the human body, which does not require an examination by the International Examining Authority in accordance with Patent Cooperation Treaty Article 17(2)(a)(i) and Rule 39.1(iv) based on the Patent Cooperation Treaty.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 20-21

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/019714

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	1-19	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO
<b>2. Citations and explanations:</b>			
<p>Document 1: Igaku no Ayumi (2000), Vol. 195, No. 1, pp. 3-8</p> <p>Document 2: Cancer therapy &amp; host (2000), Vol. 12, No. 4, pp. 363-373</p> <p>Document 3: Clinical Immunology (2002), Vol. 38, No. 4, pp. 363-369</p> <p>Document 4: Igaku no Ayumi (2002), Vol. 200, No. 6, pp. 481-486</p> <p>Document 5: Monbusho Kagakukenkyuui Hojokin ni yoru gan-juten kenkyu-hokokushu roku: Gan-kenkyuu ni kakaru juten-ryoiki kenkyu (Gan-juten) (1997), pp. 525-528</p> <p>Document 6: Hematology &amp; Oncology (1999), Vol. 38, No. 1, pp. 22-29</p> <p>Document 7: J. Immunol. (1996), Vol. 156, pp. 3159-3165</p> <p><b>Claims 1-19</b></p> <p>The inventions of Claims 1-19 do not appear to involve an inventive step over the inventions described in documents 1-7.</p> <p>Documents 1-4 describe as issues a process of inducing Th1 cells having anti-tumor activity, and their use in cancer-specific immunotherapy.</p> <p>The inventions described in documents 1-4 differ from the inventions of Claims 1-4 of this application in that they do not describe, as a process for providing antigen specificity, the introduction of a gene for a TCR which recognizes a cancer-associated antigen.</p> <p>However, documents 5-6 describe preparing cancer-specific cytotoxic T cells by introducing a gene for a cancer-specific T cell antigen receptor. Consequently, a person skilled in the art could easily conceive of manufacturing cells for cell therapy by introducing a gene for a TCR which recognizes a cancer-associated antigen described in document 5-6 into Th1 cells having anti-tumor activity to resolve the issues described in documents 1-4.</p> <p>Moreover, since it is not particularly difficult to select a publicly known cancer-associated antigen, the same applies to the invention of Claim 5. The same also applies to the invention of Claim 6 since induction with anti-CD3 antibodies and IL-2 and -12 is described in document 7. The same also applies to the inventions of Claims 7-8 since methods of preparing cells using beads or the like are merely well known technique.</p> <p>Moreover, since documents 5-6 relate to Tc cells and simultaneously providing antigen specificity to Tc cells is a matter that can be accomplished as appropriate, the inventions of Claims 9-19 is also merely a matter that would easily be conceived of by a person skilled in the art.</p>			